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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,400	08/19/2003	Che-Chun Su	P-3641.250	3991

7590 02/24/2006

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,400	SU, CHE-CHUN	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2004*. + 12/20/05

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *1-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notes of Sequence Compliance*.

DETAILED ACTION

1. Claims 1-19 are pending.

2. Applicant's election of Group III, claims 16-19 drawn to a pharmaceutical composition comprising CD30 or a biologically functional equivalent thereof and a pharmaceutically acceptable carrier, excipients or diluent filed on 12/20/05, is acknowledged. . Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 1-15 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

4. Claims 16-19 are under examination as they read on a pharmaceutical composition comprising CD30 or a biologically functional equivalent thereof and a pharmaceutically acceptable carrier, excipients or diluent.

5. Sequence compliance:
This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is required to identify the nucleotide and amino acid sequences with SEQ. ID NOS wherever sequences occur in the specification, drawings, and claims, in order to full satisfy the requirements of 37 CFR 1.821 (d) (see also MPEP 2422.02-2422.03).

Two nucleic acid sequences appear on page 27, lines 19 and 21 respectively fail to comply with the sequence rule.

6. The amendment filed 2/9/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The preliminary amendment filed on 2/9/04 to replace FIG. 3A and FIG. 3B represents a departure from the specification and the claims as originally filed. Applicant points that amended Fig 3B to clarify the numbers on the Y axis. However, the amendment is considered to introduce new matter given that there is no evidence and supporting explanation that establishes that the amended numbers in figure 3B is the same as the original material disclosed in the specification as filed.

Applicant is required to cancel the new matter in the response to this Office action.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 16-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising a soluble CD30 protein or soluble chimeric protein of CD30 for the inhibition of IL-2 release in vitro does not reasonably provide **enablement** for a "pharmaceutical" composition for "treating immune disorders" in a human comprising a thereapeutically effective amount of CD30 or "a biological functional equivalent" thereof and a pharmaceutically acceptable carrier, excipients or diluent in claim 16, wherein the CD30 or the biologically functional equivalent bidns to "CD30 ligand" in claim 19. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

Applicant has not provided sufficient biochemical information that distinctly identifies such "biologically functional equivalent" and "CD30 ligand" other than soluble CD30 and CD30-Fc and SDV peptide. While any biologically functional equivalent may have some notion of the activity of the "inhibiting the levels of T cell proliferation and/or activation", claiming biochemical molecules by such properties fails to provide sufficient guidance and direction as to how the skilled artisan can make such agents, commensurate in scope with the claimed invention. The specification fails to provide any guidance on how to make any biologically functional equivalent that can be used to inhibit the levels of T cell proliferation and/or activation *in vitro*. Similarly, besides the CD30L (CD153) the specification fails to what other ligands can bind to CD30.

It is recognized in the art that ligands must posses significant structural and chemical complementarity to their target receptors (Kuntz, Science, 1992, Vol. 257:1078-1082, especially page 10709, 2nd col., lines 1-4 and 9-12 under heading "Structure-Based Design) and that ligands generally bind to native states of proteins with little or no interaction with unfolded states (Miller et al, Protein Science, 1997, 6:2166-2179, especially page 2166, 2nd col., lines 18-20) and further that alterations in protein structure lead to alterations in bindings affinity proportional to the magnitude of the alteration (Miller et al, abstract, lines 2-4). Finally, Kuntz teaches that as little as 2% of compounds predicted to inhibit specific enzymztic or receptor systems actually shown inhibition in the micromolar range (page 1080, 3rd col.). The claims encompass alterations in protein folding because claims do permit deviation from CD30 protein for a non-native protein i.e., biologically functional equivalent. It would be reasonable to conclude that alterations in protein folding would lead to a large alteration in binding affinity.

Further, in vitro and animal model studies have not correlated well with in vivo clinical trial results in patients. Since the claimed composition is intended for treatment of immune disorders

in human indices CD30 or a biologically functional equivalent thereof that binds to CD30 ligand such as receptor/ligand-based molecules can be species – and model-dependent, it is not clear that reliance on the CD30-Fc chimeric protein that inhibits CD30/CD30L interaction which leads to the inhibition of T cell proliferation (see Example 4 and 5 of the instant specification) accurately reflects the relative efficacy of the claimed "treating immune disorders" in a human.

Also, at issue is whether or not the claimed composition would function as pharmaceutical composition. In view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the pharmaceutical composition as claimed, and absence of working examples providing evidence which is reasonably predictive that the claimed pharmaceutical composition are effective for in vivo use, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed pharmaceutical composition with a reasonable expectation of success.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagata et al (Clinical Cancer Research 8:2345-2355, July 2002).

Nagata et al teach a composition comprising human sCD30 or CD30-Fc fusion protein i.e., the extracellular domain of human CD30 fused with human IgG Fc (see abstract and Page 2346, under Recombinant CD30s in particular) in PBS (see page 2347, under ELISA in particular). The PBS solution is considered to be a pharmaceutically acceptable carrier.

Claim 19 is included because human sCD30 or CD30-Fc fusion protein would bind to CD30 ligand in the absence of evidence of structural difference.

Further the claimed functional limitation claimed in claim 16, i.e., "for treating immune disorders in a human" would be inherent properties of the referenced composition. A composition is a composition irrespective of what its intended use. The term "pharmaceutical composition" carries little patentable weight in the absence of evidence of structural difference. The the intended uses do not carry patentable weight per se and the claims read on the active or essential ingredients of the human sCD30 or CD30-Fc fusion protein.

When a claim recites using an old composition or structure (e.g. human sCD30 or CD30-Fc fusion protein) and the use is directed to a result or property of that composition or structure (treatment of immune disorders), then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

The reference teachings anticipate the claimed invention.

11. Claim 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al (Cell. 1993, 73:1349-1360).

Smith et al teach the construction of a soluble fusion protein consisting of the extracellular protein of human CD30 linked to the hinge, CH2 and CH3 domains of human immunoglobulin G1 (IgG1) heavy chain (CD30-Fc) whose ligand is CD30L (see page 1349, abstract and under results in particular). In addition, Smith et al teach a full-length CD30 is a 120kd surface antigen (see page 1349 under introduction in particular). Further, Smith et al teach that a soluble form, the entire extracellular domain of CD30 was isolated by PCR (see page 1357, under plasmid construction in particular). Also, Smith et al teaches the incubation of 2μg/ml (i.e., a composition) of CD30-Fc (see page 1357 under surface labeling and immunoprecipitations in particular). Finally, Smith et al teach a serial dilutions of CD30-Fc in binding medium in a binding assay (see page 1357 under Binding Assays in particular). The binding medium is considered to be a pharmaceutically acceptable carrier, excipients or diluent.

Further the claimed functional limitation claimed in claim 16, i.e., "for treating immune disorders in a human" would be inherent properties of the referenced composition. A composition is a composition irrespective of what its intended use. The term "pharmaceutical composition" carries little patentable weight in the absence of evidence of structural difference. The the intended uses do not carry patentable weight per se and the claims read on the active or essential ingredients of the human sCD30 or CD30-Fc fusion protein.

When a claim recites using an old composition or structure (e.g. human sCD30 or CD30-Fc fusion protein) and the use is directed to a result or property of that composition or structure (treatment of immune disorders), then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

The reference teachings anticipate the claimed invention.

12. Claim 16 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by R&D SYSTEMS (3/22/02).

The R&D SYSTEMS teaches a recombinant human CD30 (TNFRSF8)/Fc Chimera (see catalog Number: 813-CD in particular) in PBS (see Formulation and Reconstitution in particular). Further, the R&D SYSTEMS teaches the extracellular domain of human CD30/Fc chimera (amino acid residues 1-379) is fused to the carboxy-terminal Fc region of human IgG (Pro100-Lys330). In addition, R&D SYSTEMS teaches the full-length human CD30 to be expressed on different cells (see Human CD30 (TNFRSF8)/Fc chimera subtitle in particular).

The PBS solution is considered to be a pharmaceutically acceptable carrier.

Claim 19 is included because human CD30-Fc fusion protein would bind to CD30 ligand in the absence of evidence of structural difference.

Further the claimed functional limitation claimed in claim 16, i.e., "for treating immune disorders in a human" would be inherent properties of the referenced composition. A composition is a composition irrespective of what its intended use. The term "pharmaceutical composition" carries little patentable weight in the absence of evidence of structural difference. The the intended uses do not carry patentable weight per se and the claims read on the active or essential ingredients of the human CD30-Fc fusion protein.

When a claim recites using an old composition or structure (e.g. human CD30-Fc fusion protein) and the use is directed to a result or property of that composition or structure (treatment of immune disorders), then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

The reference teachings anticipate the claimed invention.

13. Claim 16 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Wiley et al 1996.

Wiley et al teach a human CD30:Fc IgG1 chimeric protein has been shown to induce gene expression and metabolic activation in human T-cells and neutrophils (see abstract in particular). Further, Wiley et al teach CD30-Fc is the extracellular domain of CD30 fused to the Fc region of human immunoglobulin (see page 3635, 1st col., last sentence under Abbreviations in particular). Finally, Wiley et al teach that the oxidative burst form neutrophils test was done in a more physiological conditions (see page 3637, 1st col., middle of 2nd paragraph in particular), wherein the DCHF-DA-soaked neutrophils were incubated for 30 min the presence of the indicated immobilized Fc fusion proteins (see Figure 3B legend in particular). The incubation in a

physiological condition indicates that the referenced CD30-Fc must be in a composition with either a carrier, excipient or diluent.

Claim 19 is included because Wiley et al teach that a strong, rapid, oxidative burst is generated by cross-linking of CD30L (CD30 ligand) by CD30-Fc (see Figs 2 and 3 in particular).

Further the claimed functional limitation claimed in claim 16, i.e., "for treating immune disorders in a human" would be inherent properties of the referenced composition. A composition is a composition irrespective of what its intended use. The term "pharmaceutical composition" carries little patentable weight in the absence of evidence of structural difference. The the intended uses do not carry patentable weight per se and the claims read on the active or essential ingredients of the human CD30-Fc fusion protein.

When a claim recites using an old composition or structure (e.g. human CD30-Fc fusion protein) and the use is directed to a result or property of that composition or structure (treatment of immune disorders), then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

The reference teachings anticipate the claimed invention.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 23, 2006

Maher Haddad

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600

Application No: 10/643,400

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821 - 1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☒ 7. Other: Two sequences appear on page 27 that fail to comply w/the sequence rule.

Applicant must provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d)

For questions regarding compliance with these requirements, please contact:

For Rules Interpretation, call (703) 308-1123
For CRF submission help, call (703) 308-4212
For PatentIn software help, call (703) 557-0400

Please return a copy of this notice with your response.